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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/586,765	07/20/2006	Lihu Yang	21556YP	1592				
<div>210 7590 10/10/2007 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907</div>								
EXAMINER RAHMANI, NILOOFAR								
<table border="1"><thead><tr><th>ART UNIT</th><th>PAPER NUMBER</th></tr></thead><tbody><tr><td>1625</td><td></td></tr></tbody></table>					ART UNIT	PAPER NUMBER	1625	
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<table border="1"><thead><tr><th>MAIL DATE</th><th>DELIVERY MODE</th></tr></thead><tbody><tr><td>10/10/2007</td><td>PAPER</td></tr></tbody></table>					MAIL DATE	DELIVERY MODE	10/10/2007	PAPER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/586,765

Applicant(s)

YANG ET AL.

Examiner

Niloofer Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-35 are pending.

Applicant's election with traverse of group II in the reply filed on 08/02/2007 is acknowledged. The applicant's traverse is on two grounds as followed:

1. There is no undue burden on the examiner to search for all of the claims, wherein X and Y differ.

2. Product, pharmaceutical composition and methods of using the claimed compounds should be rejoined.

Applicant's argument is not persuasive for the following reasons:

1. The search is extremely burden because the groups are in different classes and subclasses. Just because both group I and group II are in the same class does not indicate no undue burden. The search for each core structure is extremely burden some.

2. Rejoinder condition has been clearly delineated to applicant and if proper claim is presented for rejoinder it will be considered when any allowable compounds of group II can be identified. The method claims depend solely on the novel compounds without 112 issued should be presented for rejoinder.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12, 14-31, drawn to compound of formula (I), in part wherein X being C, Y being N are examined. Claims 13, and 32-35(full), and 1-12, and 14-

31(in part) remaining subject matter being drawn to the non-elected invention are withdrawn per 37 CFR 1.142(b).

***Priority***

2. This application is filed on 07/20/2006, which is a 371 of PCT/US05/00770, filed on 01/14/2005, which claims benefit of 60/537,732, filed on 01/20/2004.

3. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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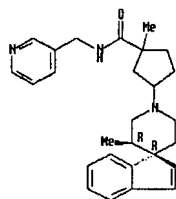
Claims 1, 7, 9, 11, 14-15, 18, 23, 25, 28, 30 are rejected under 35 U.S.C.

102(b) as being anticipated by Yang et al. US 2002/0049222. Yang et al.

disclosed the instant claimed compounds, which from the STN search is

**RN** 400763-83-9

**CN** Cyclopentanecarboxamide, 1-methyl-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]-N-(3-pyridinylmethyl)



Therefore, the instant claim is anticipated by Yang et al.

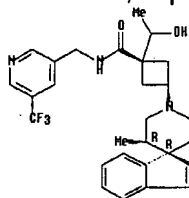
4. Claims 1, 7, 9, 11, 14-15, 18, 23, 25, 28, 30 are rejected under 35 U.S.C.

102(e) as being anticipated by Yang et al. WO 2004/082682. Yang et al.

disclosed the instant claimed compounds, which from the STN search is

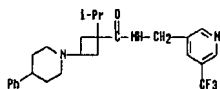
**RN** 766513-12-6

**CN** Cyclobutanecarboxamide, 1-(1-hydroxyethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]-, cis-rel



**RN** 766513-14-8

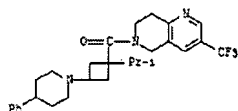
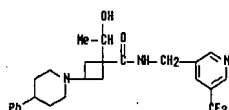
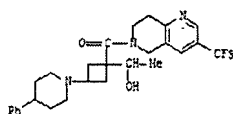
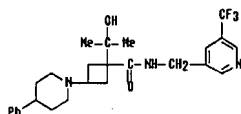
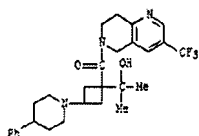
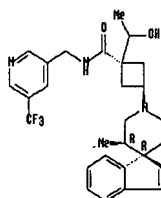
**CN** Cyclobutanecarboxamide, 1-(1-methylethyl)-3-(4-phenyl-1-piperidinyl)-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]



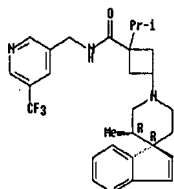
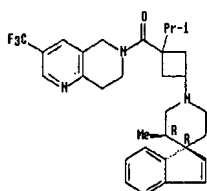
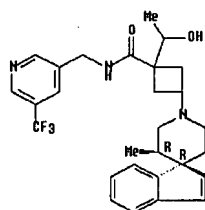
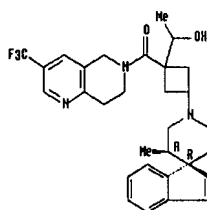
**RN** 766513-16-0

**CN** 1,6-Naphthyridine, 5,6,7,8-tetrahydro-6-[[1-(1-methylethyl)-3-(4-phenyl-1-piperidinyl)cyclobutyl]carbonyl]-3-(trifluoromethyl)

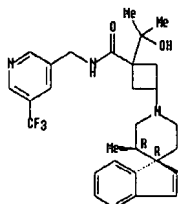
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**RN** 766513-18-2**CN** Cyclobutanecarboxamide, 1-(1-hydroxyethyl)-3-(4-phenyl-1-piperidinyl)-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]**RN** 766513-20-6**CN** 1,6-Naphthyridine, 5,6,7,8-tetrahydro-6-[[1-(1-hydroxyethyl)-3-(4-phenyl-1-piperidinyl)cyclobutyl]carbonyl]-3-(trifluoromethyl)**RN** 766513-22-8**CN** Cyclobutanecarboxamide, 1-(1-hydroxy-1-methylethyl)-3-(4-phenyl-1-piperidinyl)-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]**RN** 766513-24-0**CN** 1,6-Naphthyridine, 5,6,7,8-tetrahydro-6-[[1-(1-hydroxy-1-methylethyl)-3-(4-phenyl-1-piperidinyl)cyclobutyl]carbonyl]-3-(trifluoromethyl)**RN** 766513-57-9**CN** Cyclobutanecarboxamide, 1-(1-hydroxyethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]-, trans-rel

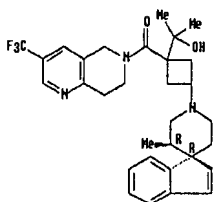
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**RN** 767332-04-7**CN** Cyclobutanecarboxamide, 1-(1-methylethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]-, rel-**RN** 767332-05-8**CN** 1,6-Naphthyridine, 5,6,7,8-tetrahydro-6-[[1-(1-methylethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]cyclobutyl]carbonyl]-3-(trifluoromethyl)-, rel-**RN** 767332-06-9**CN** Cyclobutanecarboxamide, 1-(1-hydroxyethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]-, rel-**RN** 767332-07-0**CN** 1,6-Naphthyridine, 5,6,7,8-tetrahydro-6-[[1-(1-hydroxyethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]cyclobutyl]carbonyl]-3-(trifluoromethyl)-, rel**RN** 767332-08-1**CN** Cyclobutanecarboxamide, 1-(1-hydroxy-1-methylethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]-N-[[5-(trifluoromethyl)-3-pyridinyl]methyl]-, rel-

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**RN** 767332-09-2

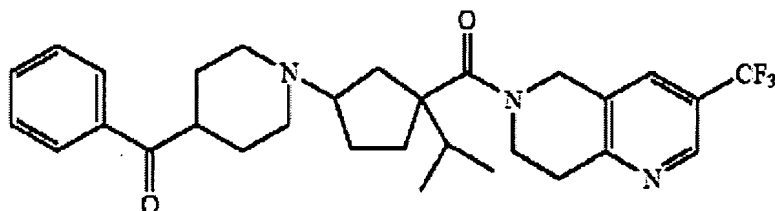
**CN** 1,6-Naphthyridine, 5,6,7,8-tetrahydro-6-[[1-(1-hydroxy-1-methylethyl)-3-[(1R,3'R)-3'-methylspiro[1H-indene-1,4'-piperidin]-1'-yl]cyclobutyl]carbonyl]-3-(trifluoromethyl)-, rel



. Therefore, the instant claim is anticipated by Yang et al.

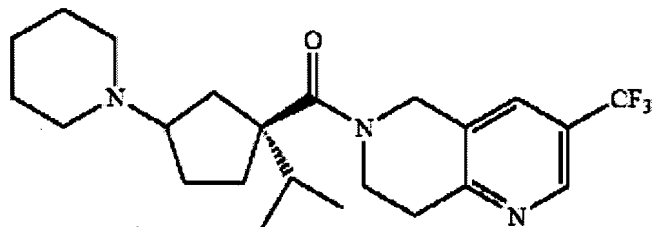
5. Claims 1, 3, 5, 7-11, 14-23, 25, 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. WO 2004/094371. Yang et al. disclosed the instant claimed compounds in Examples 1-151. Therefore, the instant claim is anticipated by Yang et al.

6. Claims 1, 3, 5, 7-11, 14-23, 25, 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbadie et al. US 2006/0205761. Abbadie et al. disclosed the instant claimed compounds in Examples II-17





Example II-19



Example II-20 to II-48 and Example II-57 and Examples II-60 to II-62 and Examples II-115 to II-133 and Examples III-1 to III-4. Therefore, the instant claim is anticipated by Abbadie et al.

**7. Claim Rejections - Obvious Double Patenting**

Claims 1-12, 14-31 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-21 of the Yang et al. US 2002/0049222. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Yang et al. claimed identical compounds in claims 1-21 as the instant claims 1-12, 14-31.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

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The issued claims 1-21 are therefore fully embraced by the instant claims 1-12, 14-31.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

**The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).**

**A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).**

**Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).**

8. Claims 1-12, 14-31 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-19 of the Yang et al. US 2006/0211,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Yang et al. claimed identical compounds in claims 1-19 as the instant claims 1-12, 14-31.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 1-19 are therefore fully embraced by the instant claims 1-12, 14-31.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

9. Claims 1-12, 14-31 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-3, 5, 7-22, 24-40 of the Goble et al. US 2006/0205783. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Goble et al. claimed identical compounds in claims 1-3, 5, 7-22, 24-40 as the instant claims 1-12, 14-31.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 1-3, 5, 7-22, 24-40 are therefore fully embraced by the instant claims 1-12, 14-31.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

**10.** Claims 1-12, 14-31 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-3 of the Goble et al. US 2006/0069088. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Goble et al. claimed identical compounds in claims 1-3 as the instant claims 1-12, 14-31.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

The issued claims 1-3 are therefore fully embraced by the instant claims 1-12, 14-31.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been issued.

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is

571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

10/03/2007

NK



D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625